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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/177,427	10/22/98	LUKAS S	

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EXAMINER	
BERMAN, M	
ART UNIT	PAPER NUMBER
1615	16

DATE MAILED: 02/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/177,427	LUKAS ET AL.	
	Examiner	Art Unit	
	Alysia Berman	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *25 October 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☒ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

1. Receipt is acknowledged of the information disclosure statement, amendment, and priority papers filed 25 October 1999. Claims 13 and 14 have been added. Claims 1-9 and 11 have been amended. Claims 1-9, 11, 13, and 14 are pending.

Specification

2. The substitute specification submitted was not entered. The substitute specification, including the claims, should be submitted as originally filed according to US practice. A copy of the PCT application that the US application claims priority from is not sufficient. A clear copy of the originally filed specification of the US application is required pursuant to 37 CFR 1.125 (a).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1, 6, 8, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4767789 (Blank et al. '789).

US '789 discloses spray-dried particles of paracetamol (acetaminophen) coated with ethyl cellulose (abstract). The amount of the coating is about 24% to 40% by weight (claim 1). The phrase "about 24%" encompasses a difference of a few percentage points. Therefore, the limitation of less than 23% coating does not render the product patentable over the prior art. Example 1 in column 2 teaches mixing the drug in a solution of ethyl cellulose and methylene chloride. The resultant mixture is spray dried to form a tasteless powder.

The reference uses a feed rate and air outlet temperatures in the process of making the particles that are within the range disclosed by Applicant at page 11, lines 2-5. Applicant defines "substantially continuous coating" as "a smooth and continuous appearance ... wherein no holes or breakage of the coating is evident so as to reduce taste masking" at page 7, lines 12-15. Since the reference uses the same process and achieves the desired results of Applicant of a coating that provides suitable taste masking, the phrase "substantially continuous coating" is not given patentable weight over the prior art. Burden is shifted to Applicant to show evidence that the referenced particles do not have a substantially continuous coating as compared to the instantly claimed invention. Claim 13 is a product-by-process claim in which the process does not render the product patentable over the prior art product.

5. Claims 1, 6, 9, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5707646 (Yajima et al. '646).

US '646 discloses a taste masked pharmaceutical formulation comprising clarithromycin (col. 2, line 55). In example 1 at column 4, particles are produced by spray drying a mixture containing clarithromycin. The particles may optionally be coated with ethyl cellulose (col. 4,

lines 11-13). Claim 13 is a product-by-process claim in which the process does not render the product patentable over the prior art product.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-8, 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4767789 (US '789).

US '789 discloses all of the limitations of the claims as stated above. The reference does not teach the core particle size, less than 20% by weight of the coating, the thickness of the coating, or the use of a two fluid nozzle spray dryer.

US '789 does teach the use of a spray dryer in general and does teach a percent of coating of about 24% by weight (see above). It is within the skill of the art to optimize parameters in order to achieve beneficial effects. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). The specific type of spray dryer is not considered critical to the invention. As disclosed by Applicant at page 10, lines 23-29, the use of a two fluid nozzle spray dryer is a preferred embodiment but is not required of the invention. It would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the parameters of the formulation of US '789 with the

reasonable expectation of achieving beneficial effects. The motivation lies in the art-recognized desire for medicaments that mask the bitter taste of some drugs.

8. Claims 1-9, 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4767789 as applied to claims 1-8, 11, 13, and 14 above, and further in view of US 5707646 (US '646).

US '789 teaches all of the limitations as stated above. The reference does not teach clarithromycin. US '646 teaches spray-dried particles of clarithromycin coated with ethyl cellulose as stated above. It would have been obvious to one of ordinary skill in the art at the time of the invention to use clarithromycin as taught by US '646 in the particles of US '789 with the reasonable expectation of providing better tasting clarithromycin particles. One of ordinary skill in the art would have been motivated to do so in order to provide more pleasant tasting medicaments.

9. Claims 1-9, 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4767789 as applied to claims 1-8, 11, 13, and 14 above, and further in view of US 4808411 (US '411).

US '789 teaches all of the limitations as stated above. The reference does not teach the core particle size or clarithromycin. As stated above, it is within the skill of the art to optimize parameters to achieve a beneficial effect. US '411 discloses a palatable composition comprising clarithromycin (abstract) in the form of fine particles that may be coated with ethyl cellulose (col. 4, lines 37-61). Note at column 4, lines 51-52, US '411 teaches that it is useful to use a particle size of less than 297 μm when using the composition to formulate a pediatric suspension.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute clarithromycin for the drug and to use a core particle size as taught by US '411 in the composition of US '789 with the reasonable expectation of providing taste masked clarithromycin particles. The motivation lies in the art-recognized need for smaller particle sizes when administering the formulation in a suspension, especially to children.

10. Claims 1-9, 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4767789 as applied to claims 1-8, 11, 13, and 14 above, and further in view of US 5378474 (US '474).

US '789 teaches all of the limitations of the claims as stated above. The reference does not teach the core particles size, less than 20% by weight of the coating, or clarithromycin. As stated above, it is within the skill in the art to optimize parameters to achieve a beneficial effect. US '474 teaches particles comprising a core containing a drug coated with a polymer hybrid coating (abstract) containing ethyl cellulose (col. 9, line 49). Formulation 1 at column 13, line 65 to column 14, lines12, teaches 14% by weight of the coating in the final product. The size of the core can be between 100 and 1700 μm depending on the amount of drug used (col. 11, lines 11-12). The core coating may have a thickness from about 5 to 200 μm (col. 8, line 67-col. 9, line 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the amount of coating, the size of the core, and the thickness of the coating as taught by US '474 in the composition of US '789 with the reasonable expectation of providing a taste masked pharmaceutical preparation with controlled release. The motivation lies in the desire for an oral medicament that provides effective blood levels of a drug over an extended period of time.

Response to Arguments

11. Applicant's arguments filed 25 October 1999 have been fully considered but they are not persuasive.

12. Applicant argues that US '789 is directed to immediate release formulations and that, in view of Deasy, one of ordinary skill in the art would not expect to produce sustained release formulations from conventional spray drying processes. Firstly, none of the claims require sustained release or taste masking. The claims as written are directed to coated particles containing a pharmaceutically active compound.

Secondly, the process by which a product is produced does not render the product patentable over the prior art. Although Deasy does state that spray coating **tends to** produce a porous particle that is not good for controlled release, the document cites an example at page 185, section 8.2.2 in which coated particles produced by spray drying exhibited sustained release properties. Therefore, it is the examiner's position that one of ordinary skill in the art would reasonably expect that spray drying could produce a sustained release product that also provides taste masking.

13. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, US '474 is relied upon merely to show that it is known in the art to use the particle sizes and percents of coating as instantly claimed. The motivation to combine the references in order to achieve the desired particle sizes and amount of coating comes from the desire for sustained release formulations that provide an effective level of a drug in the blood.

14. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703/308-4638. The examiner can normally be reached on 8:00-4:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703/308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703/305-3704 for regular communications and 703/305-3704 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-1234.

Alysia Berman
Patent Examiner
January 21, 2000

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